



Clinical Trial Details (PDF Generation Date :- Sun, 13 Jun 2021 01:56:45 GMT)

CTRI Number	CTRI/2020/06/025561 [Registered on: 03/06/2020] - Trial Registered Prospectively		
Last Modified On	13/10/2020		
Post Graduate Thesis	No		
Type of Trial	Observational		
Type of Study	Prospective Open label Observational study		
Study Design	Other		
Public Title of Study	Effect of Ayurvedic medicine in the Prophylaxis for COVID-19 of AYUSH healthcare workers , Dept of AYUSH, TS & CCRAS- NIIMH, Hyderabad.		
Scientific Title of Study	Prospective open label observational study on the effect of AYUSH-64, Samshamani vati & Chyavanprash- (Ayurvedic Raksha Kit-I) as Prophylactic measure among AYUSH healthcare workers working in the vicinity of COVID -19 facilities.		
Secondary IDs if Any	Secondary ID	Identifier	
	NIL	NIL	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Dr Srikanth Babu Perugu	
	Designation	Professor and HOD Department of Kayachikitsa	
	Affiliation		
	Address	Department of Kayachikitsa, Dr. B.R.K.R. Government Ayurvedic College SR Nagar Hyderabad-500038 TELANGANA #101, district judges quarters , road no 10,banjara hills, hyderabad 500034 Hyderabad TELANGANA 500038 India	
	Phone	9849463878	
	Fax		
	Email	drperugu@gmail.com	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	Dr Srikanth Babu Perugu
Designation		Professor and HOD Department of Kayachikitsa	
Affiliation			
Address		Department of Kayachikitsa, Dr. B.R.K.R. Government Ayurvedic College SR Nagar Hyderabad Hyderabad TELANGANA #101, district judges quarters, road no, 10, banjara hills, hyderabad-500034 Hyderabad TELANGANA 500038 India	
Phone		9849463878	
Fax			
Email		drperugu@gmail.com	
Details Contact Person (Public Query)		Details Contact Person (Public Query)	
		Name	Dr Srikanth Babu Perugu
	Designation	Professor and HOD Department of Kayachikitsa	
	Affiliation		
	Address	Department of Kayachikitsa, Dr. B.R.K.R. Government Ayurvedic College SR Nagar Hyderabad Hyderabad TELANGANA #101, district judges quarters, road no 10,banjara hills, Hyderabad- 500034 Hyderabad	



	TELANGANA 500038 India			
Phone	9849463878			
Fax				
Email	drperugu@gmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Department of AYUSH Govt. of Telangana– Ayurveda & CCRAS-NIIMH, Hyderabad			
Primary Sponsor	Primary Sponsor Details			
Name	Department of AYUSH Govt of Telangana Ayurveda CCRASNIIMH Hyderabad			
Address	Department of Ayush, Opposite passport office, Government Of Telangana			
Type of Sponsor	Research institution and hospital			
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	DrPSrikanth Babu	Dr. B.R.K.R. Government Ayurvedic College	Department of Kayachikitsa, SR Nagar Hyderabad TELANGANA Hyderabad TELANGANA	9849463878 drperuugu@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethical Committee CCRAS-NIIMH	Approved	27/05/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Ayush health workers in vicinity of COVID 19 facility	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	RAKSHA KIT-1	Chavanprash, 10 grams once aday Samshamani vati 250 mg 2 times a day & AYUSH 64 500 mg 2 times a day	
	Comparator Agent	Standard Prophylactic Care	Standard Prophylactic Care recommended by Government of Telangana Health authorities	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	68.00 Year(s)		
	Gender	Both		
	Details	1. AYUSH health care workers working within the facilities of COVID-19 duties. 2. Subjects who are from a community		



	where at least 1 confirmed case is already identified. 3. Subjects who are ready to provide written/digital informed consent and who are willing to participate and follow the protocol requirements of the clinical study 				
Exclusion Criteria	<table border="1"> <thead> <tr> <th colspan="2">Exclusion Criteria</th> </tr> </thead> <tbody> <tr> <td>Details</td> <td> Exclusion criteria: 1. Pregnant and Lactating females. 2. Known cases of uncontrolled Diabetes and Hypertension. 3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis, Cancer etc. 5. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study. 7. Subjects having a past history of allergy to any medicine that is part of the Ayurvedic intervention. 8. Other conditions, which in the opinion of the investigators, makes the patient unsuitable for enrolment or could interfere with his participation in, and completion of the protocol </td> </tr> </tbody> </table>	Exclusion Criteria		Details	Exclusion criteria: 1. Pregnant and Lactating females. 2. Known cases of uncontrolled Diabetes and Hypertension. 3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis, Cancer etc. 5. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study. 7. Subjects having a past history of allergy to any medicine that is part of the Ayurvedic intervention. 8. Other conditions, which in the opinion of the investigators, makes the patient unsuitable for enrolment or could interfere with his participation in, and completion of the protocol
Exclusion Criteria					
Details	Exclusion criteria: 1. Pregnant and Lactating females. 2. Known cases of uncontrolled Diabetes and Hypertension. 3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis, Cancer etc. 5. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study. 7. Subjects having a past history of allergy to any medicine that is part of the Ayurvedic intervention. 8. Other conditions, which in the opinion of the investigators, makes the patient unsuitable for enrolment or could interfere with his participation in, and completion of the protocol				
Method of Generating Random Sequence	Not Applicable				
Method of Concealment	Not Applicable				
Blinding/Masking	Not Applicable				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis Police personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care</td> <td>0 day and 40th day Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis AYUSH personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care</td> </tr> </tbody> </table>	Outcome	Timepoints	Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis Police personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care	0 day and 40th day Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis AYUSH personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care
Outcome	Timepoints				
Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis Police personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care	0 day and 40th day Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis AYUSH personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care				
Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>General health status of those who are taking Ayurveda preventive medicine.</td> <td>3 months</td> </tr> </tbody> </table>	Outcome	Timepoints	General health status of those who are taking Ayurveda preventive medicine.	3 months
Outcome	Timepoints				
General health status of those who are taking Ayurveda preventive medicine.	3 months				
Target Sample Size	Total Sample Size=500 Sample Size from India=500 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials				
Phase of Trial	Phase 2/ Phase 3				
Date of First Enrollment (India)	15/06/2020				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=0 Months=6 Days=0				
Recruitment Status of	Not Applicable				



Trial (Global)	
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	nil
Brief Summary	<p>in view of the no treatment available for COVID-19 infection as on date, there is a need to investigate the potential of ayurvedic preventive medicine. Classical texts of Ayurveda have emphasized the out break of such pandemics in the name of "Janapadodhwamsa" and narrated a specific preventive protocol. This is an attempt to observe the preventiive role of Ayurveda protocol in ayush personel / Healthy volunteers working in the vicinity of covid-19 facilities.</p>